JUN - 1 2001

510(k) Summary

Sponsor Information

Denver Biomedical, Inc.
14998 W. 6th Ave., Bldg. E700
Golden, CO 80401
303-279-7500

Contact Person: Jeff Hill, RA/QA Coordinator

This 510(k) summary was prepared on March 30, 2001.

Device Identification

This special 510(k) is for a modification to the Denver Pleural Effusion Shunt with External Pump Chamber. The modification is a change in the fabric to be used to manufacture the cuff that is placed on the catheters. The new cuff fabric is very similar to the existing cuff fabric, and the modified device has been found to be substantially equivalent to the original device.

Intended Use

The Denver Pleural Effusion Shunt with external pump chamber is used to palliate symptoms of recurrent pleural effusion, an accumulation of fluid in the cavity around the lungs.

Device Description

The Denver Pleural Effusion Shunt with External Pump Chamber has three major components:

3. A 15.5 Fr silicone catheter, which is implanted in the pleural space and collects the accumulated pleural effusion fluid.Part of the tubing lies in the pleural cavity, and part is external to the body. A polyester cuff on the tubing is placed in a subcutaneous tunnel. Tissue grows into the cuff to help secure the device.
4. A valved pump chamber, which remains external to the body. The patient compresses the pump chamber to transfer fluid from the pleural space to the peritoneum.
5. A second 15.5 Fr. silicone catheter, similar to the first, which passes through a subcutaneous tunnel and into the abdominal cavity. This catheter also bears a polyester cuff.

Except for the polyester cuff, all components of the shunt are made of silicone rubber.

Summary of the change

The change that was the subject of the special 510(k) was a change in the polyester material used for the cuffs. The original fabric was discontinued by the manufacturer. The fabric that will now be used is of the same basic material (polyester) and the same fabric type (double velour). It has been used as an implant for vascular surgery for over 25 years. Animal tests indicate that the fabric supports extensive tissue ingrowth, so it is expected to perform well as a cuff. Testing has verified that the fabric can bond firmly to the tubing of the shunt.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2001

Ms. Bonnie Vivian
President
Denver Biomedical, Inc.
14998 W. 6th Avenue, Bldg. E700
GOLDEN CO 80401

Re: K011020
Denver® Pleural Effusion Shunt with External Pump Chamber
Dated: May 10, 2001
Received: May 11, 2001
Regulatory Class: II
21 CFR §876.5955/Procode: 78 KPM

Dear Ms. Vivian:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K011020

Device Name: Denver Pleural Effusion Shunt w/external pump chamber

Indications For Use:

The Denver® Pleural Effusion Shunt with External Pump Chamber is indicated for adult, pediatric, and neonatal patients with chylothorax or intractable pleural effusion.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011020